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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/988,954	11/21/2001	Peter M. Bonutti	BON-1721-11	9219
33771	7590	12/23/2003		
PAUL D. BIANCO: FLEIT, KAIN, GIBBONS, GUTMAN, BONGINI, & BIANCO P.L. 601 BRICKELL KEY DRIVE, SUITE 404 MIAMI, FL 33131				
			EXAMINER PREBILIC, PAUL B	
			ART UNIT 3738	PAPER NUMBER 16

DATE MAILED: 12/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/988,954

Applicant(s)

BONUTTI, PETER M.

Examiner

Paul B. Prebilitc

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 62-70, 72-95, 97-102 and 107-115 is/are pending in the application.
- 4a) Of the above claim(s) 64-66, 68, 72-75, 77-95 and 97-102 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 62, 63, 67, 69, 70, 76 and 107-115 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 12.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

***Election/Restrictions***

Claims 64-66, 68, 72-75, 77-95, and 97-102 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 6 dated December 11, 2002.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 62, 63, 67, 70, 76, and 107-115 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

With regard to claims 62, 63, 67, 69, 70, 76 and 107-115, there is no original support for an implant that "creates a space between a body tissue and at least one other object" as claimed; see lines 2-3 of claim 62. For this reason, the Examiner posits that it constitutes new matter with respect to the original specification.

With regard to claims 110-113, there is no original, inherent, or implicit support for putting a spacer between "body tissue and bone" or between "bone and one other bone" as claimed. For this reason, the Examiner asserts that the claim language includes new matter.

With regard to claims 70, 114, and 115, it is not clear where there is original support for an implant in combination with a spacer or acting as a spacer fastened to at least one other object or to body tissue and one other object as claimed. For this reason, the Examiner asserts that the claim language constitutes new matter with respect to the original disclosure.

With regard to claims 107, 109, 111, and 113, there is no original support teaching that a space between tissues is expanded by the spacer or implant. Rather, it is only originally disclosed that the expandable material expands, not that the expansion increases the space between tissue elements. To demonstrate that this is not inherent, the Examiner asserts that the hole in bone tissue could merely be more fully filled without more space between elements being provided as claimed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 62, 63, 67, 69, 70, 76, and 107-115 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. On lines 2 and 3 of claim 62, the language of "creates a space" is unclear since creating a space or a cavity would apparently require a hollow object. This is due to the fact that "space" means "empty." For this reason, it is not clear how to interpret "creating a space" in the context of the present invention which does not provide devices with spaces or cavities in them.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 62, 63, 67, 70, 76, 108, 110, 112, and 114 are rejected under 35 U.S.C. 102(b) as being anticipated by Mears (US 4,553,272). Mears anticipates the claim language where an implant of Mears is inserted into openings in adjacent bones. This device thus creates a space (interpreted to mean a distance) between the femur (2) and the hip bone (4); see Figures 1 and 2 as well as column 3, line 26 to column 5, line 53. One implant (6) of Mears serves as the claimed implant, and the other implant (8) of Mears serves as a spacer as claimed. The expansion step is met by the expansion of the cell culture inside the body; the claim language does not require a physical or structural expansion.

With regard to claim 63, the cells of the implant of Mears inherently contain body fluid.

With regard to claim 67, the daughter cell(s) of the implant are the hydrophilic material(s) required by the claim.

Claims 62, 63, 67, 69, 70, 76, and 107 are rejected under 35 U.S.C. 102(b) as being anticipated by Kensey (US 4,890,612). Kensey anticipates the claim language where the tissue as claimed is one side of the tissue puncture, and the at least one

other object as claimed is the other side of the tissue. The implant as claimed is met by combination of the plug (102) and the toggle (106); see the abstract, Figure 9 and column 6, line 24 to column 9, line 3.

With regard to claim 76, the spacer as claimed is the plug (102) of the implant which is the combination of the plug (102) and the toggle (106).

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action.

Art Unit: 3738

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Prebilic whose telephone number is (703) 308-2905. The examiner can normally be reached on Monday-Thursday from 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for this Technology Center is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 3700 receptionist whose telephone number is (703) 308-0858.

A handwritten signature in black ink, appearing to read "Paul Prebilic", with a stylized flourish at the end.

Paul Prebilic  
Primary Examiner  
Art Unit 3738